

# EXHIBIT 3

**PRE-TRIAL ORDER**  
**EXHIBIT 3**  
**NIPPON SHINYAKU'S AND NS PHARMA'S STATEMENT OF CONTESTED FACTS**

Nippon Shinyaku and NS Pharma identify the below listed issues of contested facts for trial. To the extent that any issues of law set forth in **Exhibit 5** of the Joint Pretrial Order may be considered issues of fact, Nippon Shinyaku and NS Pharma incorporate those portions of **Exhibit 5** by reference. Should the Court determine that any issue identified in this Exhibit as an issue of fact is appropriately an issue of law, Nippon Shinyaku and NS Pharma incorporates such issue by reference into its statement of issues of law in **Exhibit 5**. By including a contested facts herein, Nippon Shinyaku and NS Pharma do not assume the burden of proof or production regarding that fact.

Nippon Shinyaku's and NS Pharma's identification of contested facts is based in part on its understanding of Sarepta and UWA's arguments regarding no willfulness, invalidity, and damages as reflected in Sarepta and UWA's interrogatory responses, expert reports, *Daubert* briefing, summary judgment briefing, and motions *in limine*. Nippon Shinyaku and NS Pharma reserve the right to address additional fact issues not set forth herein to the extent they are raised by Sarepta and/or UWA at trial. These issues of fact may change based on the Court's decisions on the pending *Daubert* motions and motions *in limine*. Nippon Shinyaku and NS Pharma provide the instant statement of contested facts based on representations Sarepta has made in the Pretrial Order cover pleading, including Sarepta's stipulation of infringement.

## **I. INFRINGEMENT OF NS PATENTS<sup>1</sup>**

1. Whether Nippon Shinyaku has proven by a preponderance of the evidence that Sarepta's infringement of each of the NS Patents has been willful due to Sarepta's knowledge of each of the NS Patents, knowledge (or the fact that it should have known of) its infringement, and continued direct and indirect infringement.

2. Whether Sarepta has failed to prove by clear and convincing evidence that any of the Asserted Claims of the NS Patents are invalid under any theory asserted by Sarepta.

## **II. INVALIDITY OF UWA PATENTS**

3. Whether Nippon Shinyaku and NS Pharma have proven by clear and convincing evidence that the Asserted Claim of the UWA Patent is invalid for failing to satisfy the written description requirement under 35 U.S.C. § 112, ¶ 1.

4. Whether Nippon Shinyaku and NS Pharma have proven by clear and convincing evidence that the Asserted Claim of the UWA Patent is invalid for failing to satisfy the enablement requirement under 35 U.S.C. § 112, ¶ 1.

## **III. UNENFORCEABILITY<sup>2</sup>**

5. Whether Nippon Shinyaku and NS Pharma have proven by clear and convincing evidence that the Asserted Claim of the UWA Patent is unenforceable due to inequitable conduct.

6.

---

<sup>1</sup> Sarepta has stipulated to infringement of the Asserted Claims of the NS Patents. Accordingly, Nippon Shinyaku and NS Pharma are relieved of any burden to adduce evidence regarding whether Sarepta has directly and/or indirectly infringed the Asserted Claims of the NS Patents.

<sup>2</sup> Evidence regarding the issues in this section will be presented during the bench trial portion of the case.

7. Whether Nippon Shinyaku and NS Pharma have proven by clear and convincing evidence that the UWA Patent specification contains one or more unmistakably false statements.

8. Whether the decision to include or failure to correct such statements amounts to affirmative egregious misconduct by Stephen Wilton or Sue Fletcher.

9. Whether Stephen Wilton or Sue Fletcher refuted inventorship of the subject matter claimed in the '851 Patent.

10. Whether prosecuting attorney Amy Mandragouras violated the duty of candor and good faith she owed to the USPTO by citing data in the '851 Patent as evidence of the truth without investigating how the data was generated or whether it was accurate.

11. Whether Nippon Shinyaku and NS Pharma have proven by clear and convincing evidence that information in Stephen Wilton or Sue Fletcher's possession but omitted from the specification is but-for material, such that the '851 Patent claims would not have issued had the correct information been disclosed to the USPTO.

12. Whether the single most reasonable inference that can be drawn from the evidence is that Stephen Wilton, Sue Fletcher, or Amy Mandragouras acted with the specific intent to deceive the USPTO.

#### **IV. DAMAGES**

13. What amount of damages are appropriate to compensate Nippon Shinyaku for the harm it incurred as a result of Sarepta's willful infringement of one or more Asserted Claims of the NS Patents.

14. .

15. What amount of lost profits and/or a reasonable royalty will compensate Nippon Shinyaku for Sarepta's infringement of the NS Patents.

16. What is the proper amount of pre- and post-judgment interest on the damages awarded.

17. Whether this case is exceptional for the purpose of awarding enhanced damages, attorneys' fees, and costs, and what is the amount of enhanced damages, attorneys' fees, and costs that should be awarded.

18. Whether Sarepta Therapeutics, Inc. or the University of Western Australia held exclusive rights to the UWA Patent during any or all time periods for which Sarepta is seeking damages.

19. Whether, and for what amount, Sarepta Therapeutics, Inc. is entitled to recover any damages during all time periods for which Sarepta is seeking damages.